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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,015	02/17/2005	Noboru Yamaji	Q86324	5025
65565 7590 06/04/2007 SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213			EXAMINER KOSAR, ANDREW D	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 06/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,015	Applicant(s) YAMAJI ET AL.	
	Examiner Andrew D. Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on January 10, 2007 and February 27, 2007 have been entered.

Response to Amendment / Arguments

Applicant's amendments and arguments filed January 10, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

With regards to the rejection of claims 11 and 13-15 as anticipated by SKOV, the rejection is withdrawn, as the patient population of Skov is sufficiently distinguished from the instant patient population.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 13-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by KAMMER (PTO-1449, 6/24/05) for the reasons of record and those set forth below.

Applicant argues that administration to “a patient in need thereof” distinguishes the patient population. Applicant further argues that Kammer “implies that the autoimmune diseases

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include a broad range of disease from systemic diseases to local ones. In actuality, however, Kammer merely shows an improvement in proteinuria...and there is no disclosure of a specific effect on rheumatic arthritis (joint) therein.” (page 5, remarks 11/27/06).

Respectfully, the examiner disagrees, as Kammer specifically claims treating rheumatoid arthritis (herein ‘RA’) with the HDACi (referenced below). Since ACEM is an underlying condition/feature of RA, in treating RA, one is necessarily inhibiting ACEM degradation.

The instant claims are presented *supra* and are further drawn to treating ACEM in arthroseitis, rheumatoid arthritis (herein ‘RA’) or osteoarthritis and to treating RA, arthroseitis or osteoarthritis caused by ACEM.

The teachings of Kammer have been presented previously (*see* Office Action 4/20/06, pages 11-12). Kammer teaches a method of treating RA with a histone hyperacetylating agent (claim 10). In looking to the specification for the preferred embodiments of the histone hyperacetylating agent usable in the method, the specification provides that HDACi are the preferred compounds (citing WO 97/11366), providing exemplary HDACi usable in the methods, including trichostatin A, SBHA, SAHA, apicidin (e.g. *Specification* pages 6-8) and specifically embodies in the claims (e.g. claims 3-9) trichostatin A, trapoxin A, FK228 (FR901228) and MS-275 (MS-27-275). Kammer teaches that the compounds are preferably administered at 1 $\mu\text{mol/kg}$ to 50 $\mu\text{mol/kg}$, more preferably at 22 $\mu\text{mol/kg}$ to 33 $\mu\text{mol/kg}$ for oral and i.v. administration, thus being of an overlapping, if not commensurate scope of the instantly disclosed preferred dosages. Further, in treating RA one would be treating/inhibiting the underlying conditions, e.g. ACEM. Additionally, it is noted that Applicant admits in the instant

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specification that Kammer teaches treating RA with HDACi (spanning pages 6-7 of the instant specification).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D. Kosar/
Andrew D Kosar
Patent Examiner, Art Unit 1654